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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/234,208	01/20/1999	JONI KRISTIN DOHERTY	49321-1	6406

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DAVIS WRIGHT TREMAINE, LLP
2600 CENTURY SQUARE
1501 FOURTH AVENUE
SEATTLE, WA 98101-1688

EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/234,208

Applicant(s)

DOHERTY ET AL.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8-10,18-20,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3 and 8-10 is/are allowed.
- 6) ☒ Claim(s) 18 is/are rejected.
- 7) ☒ Claim(s) 19,20,27 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 22.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed Nov. 22, 2002 is acknowledged. Claims 21 and 22 (renumbered 27 and 28, per 37 CFR 1.126) were added.

Claims 1-3, 8-10, 18-20, 27 and 28 are pending and examined on the merits.

2. The declarations Dr. Edward Neuwelt and Dr. Gail M. Clinton have been considered.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

4. The rejection of claims 3 and 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment deleting the phrase "at least in part distinct".

5. The rejection of claims 1-3, 8-10 and 18-20 35 U.S.C. 112, first paragraph, because the specification is not commensurate in scope with the scope of the claimed inventions, is withdrawn in view of applicant's arguments and the amendment to claims 3 and 10.

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6. The rejection of claims 18-20 under 35 U.S.C. 112, first paragraph, for lack of enablement, is withdrawn in view of applicant's arguments and in view of the declarations of Dr. Edward Neuwelt and Dr. Gail M. Clinton.

New Grounds of Rejection:

7. Claims 27 and 28 are objected to because they appear to be of exactly the same scope as claims 3 and 10. Claims 27 and 3 are both drawn to polypeptides that consist of SEQ ID NO: 1. Claims 28 and 10 are both drawn to polypeptides that consist of SEQ ID NO: 2. Claims 3 and 10 are dependent from claims 1 and 8, respectively. However, this dependency does not result in scope that is different from that of claims 27 and 28, respectively, because the recitation of affinity binding constant is a recitation of an inherent feature of the claimed species of polypeptide.

8. Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Hudziak (U.S. Patent 6,399,063; issued June 4, 2002; effective filing date Jan. 25, 1988).

Claim 18 recites pharmaceutical compositions that comprise an agent that is a monoclonal antibody that binds to the extracellular domain of Her-2 in combination with at least a second agent. Hudziak discloses pharmaceutical compositions comprising an antibody to Her-2 and a second agent, such as a cytokine (TNF-alpha, TNF-beta, IL-2, IL-2, Interferon-gamma; see col. 7, lines 3 – 61; claims 8-13). Thus, Hudziak discloses the claimed pharmaceutical compositions.

Conclusion


Claims 1-3, 8-10 are allowed. Claims 19, 20, 27 and 28 are objected to. Claim 18 is rejected. Claims 19 and 20 would be allowable if rewritten as independent claims.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
March 10, 2003


ANTHONY C. CAPUTA
SUPERVISOR
TECHNOLOGY CENTER 1600